

### **REMARKS / ARGUMENTS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, as amended, pursuant to and consistent with 37 C.F.R. § 1.111, are respectfully requested.

#### **Amendments to the Claims and Support for Amendments**

Claims 21-47 are pending in the application and have been amended by the foregoing amendments to the claims.

In particular, claims 21, 31 and 45 have been amended to replace the phrase “*in a form of microcrystals or microgranules that are uniformly coated with a polymer coating*” with the phrase “*in a form of microcrystals that are uniformly coated with a polymer coating or of microgranules that are uniformly coated with a polymer coating*”. Support for this amendment can be found throughout the specification of the application, as originally filed, in particular in the Examples. For instance, in Example 1, microcrystals of paracetamol are sprayed with a dispersion of EUDRAGIT E100, EUDRAGIT NE 30 D and colloidal silica in ethanol to obtain microcrystals coated with a polymer coating of the formulation given in Table 2. Similarly, in Example 2, microgranules of ibuprofen are uniformly coated with a polymer coating comprising ethylcellulose, precipitated silica and hydroxypropylmethylcellulose (see Table 4). In Example 3, microgranules of paracetamol are coated with ethylcellulose, hydroxypropylmethylcellulose and colloidal silica (see Table 6).

Other amendments to the claims have also been made to clarify the claim language, for consistency, and to bring the claims into better conformance with U.S. patent practice. These amendments are merely editorial in nature and are not intended to change the scope of the claims or any elements recited therein.

The amendments to the claims have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments to the above-identified application are respectfully requested.

**Response to Rejections under 35 U.S.C. § 103**

The Examiner has maintained the rejection of claims 21-41 under 35 U.S.C. § 103(a) as allegedly being obvious over Hunter *et al.* (U.S. Pat. No. 6,391,337) in view of Schmitz *et al.* (U.S. Pat. No. 6,079,968) and Valentine (U.S. Pat. No. 4,684,534); and the rejection of claims 31 and 42-47 under 35 USC § 103(a) as allegedly being obvious over Hunter *et al.* in view of Schmitz *et al.*

In particular, the Examiner has interpreted the term “*microcrystals or microgranules that are uniformly coated with a polymer coating*” to mean that the active substance may be in the form of uncoated microcrystals, or in the alternative, in the form of microgranules that are uniformly coated with a polymer coating, and has concluded that, given the teachings of U.S. Patent No. 6,391,337, it would have been obvious to one skilled in the art to use uncoated microcrystals of acetaminophen in the direct compressed dosage forms of the invention. This rejection is respectfully traversed.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the claims have been amended as described above. Specifically, the claims now recite “*an active substance in a form of microcrystals that are uniformly coated with a polymer coating or of microgranules that are uniformly coated with a polymer coating*”. The rejection is now moot since the prior art references fail to explicitly or implicitly disclose all of the claim limitations as required to support a *prima facie* case of obviousness. As previously submitted, the cited references, taken alone or in combination, do not teach or suggest a tablet that disintegrates in the mouth on contact with saliva in less than 30 seconds forming an easy-to-swallow suspension and that contains an active substance in the form of microcrystals that are uniformly coated with a polymer coating or in the form of microgranules that are uniformly coated with a polymer coating (see, e.g., the Amendment filed on March 13, 2009 for more detail). Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Response to Rejection under 35 U.S.C. § 112, First Paragraph**

Claims 21-47 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

More specifically, the Examiner has asserted that there is no support for a “uniformly coated” microgranule in the specification, and that consequently a skilled practitioner would not believe that the Applicant had possession of the invention at the time of filing. This rejection is respectfully traversed.

It is well established that there is no *in haec verba* requirement, that is, claim terms added by amendment need not be found word-for-word in a specification. *See* M.P.E.P. § 2163.I.B. Newly added claim limitations can be supported in the specification through express, implicit, or inherent disclosure. *Id.* The test for determining whether the specification provides an adequate written description of the claimed invention is whether the originally filed specification disclosure reasonably conveys to a person having ordinary skill that applicant had possession of the subject matter later claimed. *See, e.g., Ex Parte Sorenson*, 3 USPQ 2d 1462, 1463 (PTO Bd. App. & Int. 1987).

Applicant respectfully submits that one of ordinary skill in the art would have fully appreciated upon reviewing the present application that the Applicant intended the polymer coating to be uniformly distributed on the outer surface of the microcrystals or microgranules of active substance (*i.e.*, to cover the entire outer surface of the microcrystals or microgranules of active substance).

For instance, in Example 1, before being used in the preparation of tablets according to the invention, “*microcrystals of paracetamol are fed in a fluid-bed plant and a dispersion of EUDRAGIT E 100, EUDRAGIT NE 30 D and colloidal silica in ethanol is sprayed onto the microcrystals to obtain microcrystals coated with 10% of polymer*” (page 8, lines 2-5). It would have been obvious to one skilled in the art that this spraying results in the polymer covering the entire surface of the microcrystals. It would also have been obvious to one skilled in the art that if, for some reason, the Applicant had intended the surface of the microcrystals to be only partially covered with polymer, a different “coating” technique would have been used or specific measures would have been taken to allow the sprayed polymer to only reach a fraction of the microcrystal's surface. Therefore, Applicant submits that the description, as originally filed, contains support for a “uniformly coated” microgranule or microcrystal, and requests that the rejection under 35 U.S.C. § 112, first paragraph be removed.

**CONCLUSION**

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

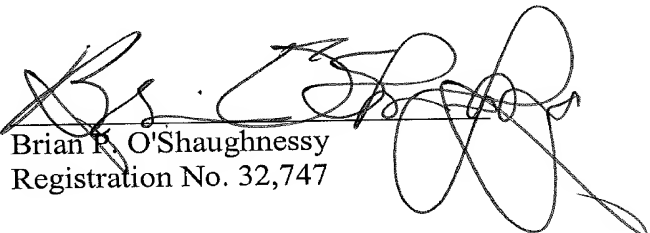
The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: August 3, 2009

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